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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/139,058	08/24/1998	MARTIN C. WOODLE	5325-0122.20	4881

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/139,058

**Applicant(s)**

WOODLE ET AL.

**Examiner**

Gollamudi S Kishore, Ph.D

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8,9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8,9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The amendment and letter dated 1-12-04 are acknowledged.

Claims included in the prosecution are 8-9 and 11-19.

The following are the new rejections.

#### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 8-9 and 11-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 9, 18-19 and 24-26 of U.S. Patent No. 5,225,212. Although the conflicting claims are not identical, they are not patentably distinct from each other because both patented claims and instant pending claims recite liposome compositions containing lipid derivatized with hydrophilic polymers, polyglycolic acid (PGA) and polylactic acid (PLA) and polyvinyl alcohol. The liposomes in the patented claim 1 are generic with respect to the active agent and the specification discloses gentamicin claimed in instant claims. Instant method of preparation claims are

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nominal claims which recite only 'entrapping the agent' which is fully disclosed in the specification of the patent and also covered by the patented composition claims since the patented claims recite entrapped agent.

3. Claims 8-9 and 11-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,013,556 in view of either JP 60239417 or Allison et al (5,376,369).

Claims in 5,013,556 are drawn to liposomal compositions containing 1-20 mole percent of an amphipathic, vesicle-forming lipid derivatized with a polyethylene glycol (PEG) and containing a compound in liposome entrapped form with sizes between 0.05 and 0.5 microns. What is not claimed in the patented claims is the instantly claimed hydrophilic (water-soluble) polymer, polyvinyl alcohol (PVA).

JP teaches that PVA and PEG are both water-soluble polymers (abstract).

Similarly Allison et al teach that PVA and PEG are surfactants (col. 8, line 63 through col. 9, line 12).

The use of water soluble hydrophilic polymer such as PVA instead of PEG in 5,013,556 would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the references of JP and Allison show that they are art well-known equivalents. It should be pointed out that on page 9 of instant specification also indicate the equivalency between PVA and PGA in terms of their hydrophilic nature and function.

***Claim Rejections - 35 USC § 102***

4. Claims 8-9 and 11-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Martin et al (5,225,212) cited above.
5. Martin et al disclose recite liposome compositions containing lipid derivatized with hydrophilic polymers, polyglycolic acid (PGA) and polylactic acid (PLA). The liposome sizes disclosed are 0.1 to 0.4 microns and the active agents disclosed are AZT, ribavirin, acyclovir (antiviral agents) and antibiotic, gentamicin (abstract, col. 12, lines 35-42 and claims).

***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 8-9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodle et al (5,013,556) in view of either JP 60239417 or Allison et al (5,376,369).

Woodle teaches liposomal compositions containing 1-20 mole percent of an amphipathic, vesicle forming lipid derivatized with a polyethylene glycol (PEG) and containing a compound (gentamicin) in liposome entrapped form with sizes between 0.05 and 0.5 microns (abstract, col. 11, line 61 and claims). What is lacking in Woodle is the instantly claimed hydrophilic (water-soluble) polymer, polyvinyl alcohol (PVA).

JP teaches that PVA and PEG are both water-soluble polymers (abstract).

Similarly Allison et al teach that PVA and PEG are surfactants (col. 8, line 63 through col. 9, line 12).

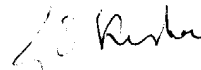
The use of water soluble hydrophilic polymer such as PVA instead of PEG in 5,013,556 would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the references of JP and Allison show that they are art well-known equivalents. It should be pointed out that on page 9 of instant specification also indicate the equivalency between PVA and PGA in terms of their hydrophilic nature and function.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM-4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK